



10 July 2023

Hemogenyx Pharmaceuticals plc

("Hemogenyx Pharmaceuticals" or the "Company")

Full FDA Review for HEMO-CAR-T IND

Hemogenyx Pharmaceuticals plc (LSE: HEMO), the biopharmaceutical group developing new therapies and treatments for blood diseases, announces that the Company has received a full review letter from the U.S. Food and Drug Administration ("FDA") regarding the Investigational New Drug ("IND") application for the Company's product candidate Chimeric Antigen Receptor ("CAR") T-cells ("HEMO-CAR-T") for the treatment of acute myeloid leukaemia ("AML") to the effect that HEMO-CAR-T be put on clinical hold ("CH"). The letter contains a detailed description of the rationale for the decision to put HEMO-CAR-T IND on CH. The reason for the CH relates to a splicing that occurs during the manufacturing process of the lentivirus that is used to produce CAR-T cells. The Company has identified the source of the splicing deficiency and has already developed a method to eliminate it. The lentivirus is being remanufactured. The CH letter also contains several suggestions on how to improve the safety of HEMO-CAR-T. These suggestions do not and would not contribute to the CH and can be dealt with readily.

Dr Vladislav Sandler, CEO & Co-Founder of Hemogenyx Pharmaceuticals, commented: *"We are confident that we will be able to address the FDA's questions and concerns regarding the IND. AML has poor survival rates and we are eager to resolve this hold and continue down the treatment development pathway toward saving lives."*

About AML and CAR-T Therapy

AML, the most common type of acute leukemia in adults, has poor survival rates (a five-year survival rate of less than 30% in adults) and is currently treated using chemotherapy, rather than the potentially more benign and effective form of therapy being developed by Hemogenyx Pharmaceuticals. The successful development of a new therapy for AML would have a major impact on treatment and survival rates for the disease.

CAR-T therapy is a treatment in which a patient's own T-cells, a type of immune cell, are modified to recognize and kill the patient's cancer cells. The procedure involves: isolating T-cells from the patient; modifying the isolated T-cells in a laboratory using a CAR gene construct (which allows the cells to recognize the patient's cancer); amplifying (growing to large numbers) the newly modified cells; and re-introducing the cells back into the patient.

Market Abuse Regulation (MAR) Disclosure

Certain information contained in this announcement would have been inside information for the purposes of Article 7 of Regulation No 596/2014 (as it forms part of UK domestic law by virtue of the European Union (Withdrawal) Act 2018) until the release of this announcement. The person responsible for arranging for the release of this announcement on behalf of Hemogenyx Pharmaceuticals plc is Dr Vladislav Sandler, Chief Executive Officer & Co-Founder.

Enquiries:

Hemogenyx Pharmaceuticals plc

Dr Vladislav Sandler, Chief Executive Officer & Co-Founder

Peter Redmond, Director

<https://hemogenyx.com>

headquarters@hemogenyx.com

peter.redmond@hemogenyx.com

SP Angel Corporate Finance LLP

Matthew Johnson, Vadim Alexandre, Adam Cowl

Tel: +44 (0)20 3470 0470

Peterhouse Capital Limited

Lucy Williams, Duncan Vasey, Charles Goodfellow

Tel: +44 (0)20 7469 0930

About Hemogenyx Pharmaceuticals plc

Hemogenyx Pharmaceuticals is a publicly traded company (LSE: HEMO) headquartered in London, with its US operating subsidiaries, Hemogenyx Pharmaceuticals LLC and Immugenyx LLC, located in New York City at its state-of-the-art research facility.

The Company is a pre-clinical stage biopharmaceutical group developing new medicines and treatments to treat blood and autoimmune disease and to bring the curative power of bone marrow transplantation to a greater number of patients suffering from otherwise incurable life-threatening diseases. Hemogenyx Pharmaceuticals is developing several distinct and complementary product candidates, as well as platform technologies that it uses as engines for novel product development.